K081143

BioMers

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MAY - 2 2008

510(k) Summary
(per 21 CFR 807.92)

I. Applicant

BioMers Products, LLC.
2316 Pine Ridge Road, Suite 459
Naples, FL, 34109

Contact Person: George Aliphtiras, Vice President of Operations
Tel: (239) 776-6344
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Date Prepared: December 19, 2007

II. Device Name

Proprietary Name:	BioMers Translucent Orthodontic Wire
Common/ Usual Name:	Orthodontic wire
Classification Name:	Orthodontic appliance and accessories
Regulation Number:	872.5410
Product Codes:	DZC
Classification:	I
Classification Panel:	Dental

III. Predicate Device

The BioMers Translucent Orthodontic Wire is substantially equivalent to the Optiflex from Ormco Corp. and the Super Elastic Nickel Titanium Arch Wire from Acme Monaco Corp. The Optiflex was cleared by the FDA on September 15, 1989 under 510(k) K894781. The Super Elastic Nickel Titanium Arch Wire is exempt from 510(k) filings.

IV. Intended Use of the Device

The BioMers Translucent Orthodontic Wire is indicated for use as an orthodontic arch wire to provide force to the teeth to effect movement in the early (leveling and aligning) stage of orthodontic treatment.

V. Description of the Device

The BioMers Translucent Orthodontic Wire is a translucent arch wire comprised of glass fibers, a polymer composite resin, and a polymer coating. The embedded glass fibers function as the reinforcement, providing the necessary force to straighten teeth. The translucent polymer composite resin serves as the matrix, binding together the individual glass fibers. The outer coating, made of a USP Class VI polycrystalline and amorphous linear polymer, increases theabrasion resistance properties of the wire.

VI. Summary of the Technical Characteristics

The BioMers Translucent Orthodontic Wire is an orthodontic arch wire used to provide force to the teeth to effect movement in the early (leveling and aligning) stage of orthodontic treatment. The BioMers Translucent Orthodontic Wire was designed and tested using the following standards:

- ASTM D 790 - 03 Standard test methods for flexural properties of unreinforced and reinforced plastics and electrical insulating materials
- ASTM D 3916 - 02 Standard test method for tensile properties of pultruded glass fiber reinforced plastic rods
- ASTM D 570 - 98 (Reapproved 2005) Standard test method for water absorption of plastics

VII. Safety & Effectiveness

There are no known substantial differences between the BioMers Translucent Orthodontic Wire defined in this 510(k) submission and the predicate devices. They have the same intended use and any differences in technological characteristics do not raise issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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BioMers Products, LLC
C/O Mr. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services NA, Incorporated
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

Re: K081143
Trade/Device Name: BioMers Translucent Orthodontic Wire
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: DYW, DZC
Dated: April 21, 2008
Received: April 22, 2008

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

BioMers

4. Indication for Use Statement

510(k) Number (if known):

Device Name: BioMers Translucent Orthodontic Wire

Indications for Use:

- An orthodontic arch wire used to provide force to the teeth to effect movement in the early (leveling and aligning) stage of orthodontic treatment.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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